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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/943,318 | 08/31/2001 | James Norman Cawse | rd-28,249 | 8731 |

6147 7590 01/29/2004

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| EXAMINER | |
|---|---|
| MORAN, MARJORIE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/943,318 | CAWSE, JAMES NORMAN | |
| | Examiner | Art Unit | |
| | Marjorie A. Moran | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *3-10,12-14 and 23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,11 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

***Election/Restrictions***

Applicant's election of Group I, claims 1-25 and species of Graeco-Latin square design, Analysis of Variance, and a Group VIII B metal in the response filed 10/28/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-10, 12-14, and 23-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/28/03. It is noted that claims 6-7 and 9-10 were incorrectly listed as "generic" in the restriction/election of species requirement mailed 9/30/03. The examiner regrets the error. As claims 6-7 and 9-10 do not read on a space defined by a Graeco-Latin square design, they are considered nonelected and are withdrawn, as set forth above.

An action on the merits of elected claims 1-2, 11, 15-22, as they read on the elected species, follows.

***Information Disclosure Statement***

The IDS filed 8/22/02 has been considered. It is noted that applicant has a variety of copending applications claiming similar subject matter to that of the instant claims, which copending applications have not been listed in an IDS nor otherwise disclosed in the instant application. See e.g. the double patenting rejection below. Applicant is reminded of the duty to disclose information material to patentability.

***Double Patenting***

Claims 1, 15, 16-19, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 14-17, and 18, respectively of U.S. Patent No. 6,684,161 (due to be published 1/27/04) in view of GORE (J. Indust. Eng. Chem. (1950) vol. 42, pages 320-323) and MILLIKEN et al. (Analysis of Messy Data, Volume I (1992) Chapman and Hall, London, UK, pages 47-62).

Instant claim 1 recites a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels (results). Instant claim 15 limits the experimental space to be defined by two or more factors, wherein each factor comprises a plurality of possible levels. Claims 16-17 limit the CHTS to comprise parallel chemical reactions of an array; and to chemical reactions on a micro scale. Claim 18 limits the CHTS to an iteration of steps with tagged reactants and identification of tagged products. Claim 19 limits the CHTS to iteration of steps comprising evaluation of products of the reactions (results) before performance of the next step. Claim 22 limits the chemical space to comprise a Group VIII B metal.

Claim 1 of '161 recites a method of selecting a best case of levels of a reaction by defining an experimental space comprising levels of factors according to an incomplete block design and separately effecting a CHTS experiment on the

experimental space and selecting a set of best results. Claim 2 limits the experimental space to comprise multiple factors, wherein the factors comprise a plurality of levels. Claims 14-15 limit the CHTS to comprise parallel chemical reactions of an array; and to chemical reactions on a micro scale. Claim 16 limits the CHTS to an iteration of steps with tagged reactants and identification of tagged products. Claim 17 limits the CHTS to iteration of steps comprising evaluation of products of the reactions (results) before performance of the next step. Claim 18 limits the chemical space to comprise a Group VIII B metal. It is noted that '029 defines a Latin square as a type of incomplete block design (paragraph 15). The claims of '161 do not recite defining an experimental space according to a Latin square strategy.

GORE teaches use of Latin Square design to define factors/levels in a catalyzed chemical reaction (pp. 322-323) and teaches that use of a Latin Square strategy is an improvement over other statistical calculations of catalytic reaction conditions because it allows for interactions between factors to be evaluated (p. 322). MILLIKEN provides support that "incomplete block" and Latin square are both "block-type" statistical designs which may be used in analysis of similar data (p. 47).

It would have been obvious to one of ordinary skill in the art at the time of invention to have defined the experimental space in the method of '029 using a Latin square strategy, as taught by both GORE and MILLIKEN, where the motivation would have been to use any known "block" type of statistical analysis and where use of a Latin square strategy would have allowed interactions between factors in the experimental space, as taught by GORE.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 11, and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a set of "factor levels" in line 1. The specification provides support on p. 4 for a method of determining reactant factors and their levels. Based on the disclosure of page 4, a "factor" is interpreted to be a reactant factor; however, a factor "level" is not defined anywhere in the specification or claims. A "level" may be defined in many ways; e.g. concentration relative to another level, concentration relative to a total (wherein the "total" may be volume, mass, number of reactants, etc.), units added or present (e.g. volume or mass), etc. As the term "level" with regard to a reactant factor may have many meanings in the art and is not defined by the instant specification or claims, one skilled in the art would not know the metes and bounds of the claim intended by applicant, and the claim is indefinite.

Claims 1 and 21 recite the term "best case" with regard to a set of factor levels. It is unclear what is intended to be a "best case" of factor levels; i.e. is a "best case set"of a catalyzed reaction intended to be the set of reactant levels which provides the fastest reaction time, or the set which results in the least amount of waste of reactants, or the least heat of reaction, or which results in the greatest amount of product, or which

produces product with the particular (desired) properties? As it is unclear what applicant intends as a "best case set" of factor levels, the claims are indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 15-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over GORE et al. GORE (J. Indust. Eng. Chem. (1950) vol. 42, pages 320-323) in view of WOLF et al. (IDS ref: Appl. Catalysis (2000) vol. 200, pp. 63-70), supported by CAWSE et al. (The 1999 ASA Quality and Productivity Research Conference, Schenectady, NY).

Claim 1 recites a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels (results). Claim 15 limits the experimental space to be defined by two or more factors, wherein each factor comprises a plurality of possible levels. Claims 16-17 limit the CHTS to comprise parallel chemical reactions of an array; and to chemical reactions on a micro scale. Claim 19 limits the CHTS to iteration of steps comprising evaluation of products of the reactions before performance of the next step. Claim 20 limits the evaluating step of claim 19 to identify relationships between factor

levels and determining the chemical space according to a Latin square design before the next iteration. Claim 21 limits the method to comprise iterations of reactions until a "best set" of factor levels is selected. Claim 22 limits the chemical space to comprise a Group VIII B metal.

GORE teaches a method of determining a best case of factor levels by defining a catalyzed chemical experimental space according to a Latin square strategy and effecting tests of different combinations of factors to select a best case set of factor levels (pp. 322-323). GORE's experimental space comprises at least two factors, each of which may comprise a plurality of levels (p. 323: Summary), GORE teaches that his experimental space comprises reactants, catalysts, and conditions, and teaches evaluation of a set of reactant conditions and determining an experimental space by his Latin square strategy before a next iteration of factor conditions (p. 323, right column). GORE does not teach a CHTS method for screening.

WOLF teaches that CHTS methods maybe used to screen chemical combinations of catalytic factors (p. 64), wherein a catalyst may comprise iron (a Group VIII B metal, p. 66). WOLF further teaches that a second generation of a catalytic conditions (factor levels) maybe chosen based on the results of a first CHTS method, and teaches iterations of the method to choose a best case set of factor levels (pp. 74-75). WOLF teaches effecting his CHTS experiments on a micro-scale (p. 72).

CAWSE teaches that a combination of a Latin Square design with combinatorial strategies is desirable for designing conditions for catalytic mixtures.

It would have been obvious to one of ordinary skill in the art to have combined the CHTS screening, micro-scale testing and iterations of WOLF with the Latin square analysis in the method of GORE where the motivation would have been to increase efficiency, as taught by WOLF (p. 63) and where CAWSE teaches that a combination of combinatorial testing and Latin square strategy are desirable. It would further have been obvious to have performed the method of GORE and WOLF on materials including a Group VIIIB metal such as the iron of WOLF where the motivation would have been to improve the amount and/or quality of the product of any catalytic mixture, as taught by both GORE and WOLF.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over GORE et al. GORE (J. Indust. Eng. Chem. (1950) vol. 42, pages 320-323) in view of WOLF et al. (IDS ref: Appl. Catalysis (2000) vol. 200, pp. 63-70), supported by CAWSE et al. (The 1999 ASA Quality and Productivity Research Conference, Schenectady, NY) as applied to claims 1, 15-17 and 19-22 above, and further in view of GLEMITE et al. (Latvijas PSR Zinatnu Akad. Vestis (1971) vol. 3, pp. 365-371).

Claim 1 recites a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels (results). Claim 2 limits the space to be defined by a Graeco-Latin square design.

GORE, WOLF, and CAWSE make obvious a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels, as set forth above. None of GORE, WOLF or CAWSE specifically teach a Graeco-Latin square strategy.

GLEMITE teaches that catalytic reactions may be analyzed using Greek-Latin squares (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have analyzed the data in the method of GORE, WOLF, and CAWSE using the Greek-Latin squares of GLEMITE where the motivation would have been to select an optimal combination of factor conditions (levels) using a combined method of analysis, as taught by GLEMITE.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over GORE et al. GORE (J. Indust. Eng. Chem. (1950) vol. 42, pages 320-323) in view of WOLF et al. (IDS ref: Appl. Catalysis (2000) vol. 200, pp. 63-70), supported by CAWSE et al. (The 1999 ASA Quality and Productivity Research Conference, Schenectady, NY), further in view of GLEMITE et al. (Latvijas PSR Zinatnu Akad. Vestis (1971) vol. 3, pp. 365-371) as applied to claims 1-2, 15-17 and 19-22 above, and further in view of JACOB et al. (US 5,741,460).

Claims 1-2 recite a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square

strategy, specifically a Graeco-Latin square design, and effecting a CHTS experiment on the experimental space to select a best case set of factor levels (results). Claim 11 limits the method to one wherein results of the CHTS method are analyzed by analysis of variance.

GORE, WOLF, CAWSE, and GLEMITE make obvious a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels, as set forth above. None of GORE, WOLF, CAWSE or GLEMITE specifically teach analysis of variance.

JACOB teaches that analysis of variance maybe used to analyze data resulting from Graeco-Latin square design experiments in analyzing a chemical space (col. 23, lines 11-22).

It would have been obvious to have used the analysis of variance taught by JACOB to analyze data in the method of GORE, WOLF, CAWSE, and GLEMITE where the motivation would have been to perform statistical analysis on results of a Graeco-Latin square design of a chemical space, as taught by JACOB.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over GORE et al. GORE (J. Indust. Eng. Chem. (1950) vol. 42, pages 320-323) in view of WOLF et al. (IDS ref: Appl. Catalysis (2000) vol. 200, pp. 63-70), supported by CAWSE et al. (The 1999 ASA Quality and Productivity Research Conference, Schenectady, NY) as

applied to claims 1, 15-17 and 19-22 above, and further in view of AGRAFIOTIS et al. (US 5,901,069).

Claim 1 recites a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels (results). Claim 18 limits the CHTS to an iteration of steps with tagged reactants and identification of tagged products.

GORE, WOLF, and CAWSE make obvious a method of selecting a best case of levels of a catalyzed chemical reaction by defining an experimental space according to a Latin square strategy and effecting a CHTS experiment on the experimental space to select a best case set of factor levels, as set forth above. None of GORE, WOLF or CAWSE specifically teach use of tagged reactants or identifying tagged products.

AGRAFIOTIS teaches a method of analyzing chemical space in an iterative fashion, wherein a next set of steps is selected based on the results of a previous analysis, and teaches that product composition (results) may be analyzed by decoding molecular tags (col. 10, lines 36-40).

It would have been obvious to one of ordinary skill in the art at the time of invention to have tagged reactants and identified tagged products, as taught by AGRIFIOTIS, in the method of GORE, WOLF, and CAWSE where the motivation would have been to facilitate choosing a next set of steps in the iterative process, as taught by AGRAFIOTIS.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0549.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

mam